

FFA-305 Division of Biologics
Management
no cc

Date of Approval: AUG 10 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 128-409

IVOMEC (ivermectin) Injection for Cattle and Swine

"In cattle to extend the period of persistent effect for *Oesophagostomum radiatum* from 14 to 28 days and for *Trichostrongylus axei* and *Cooperia punctata* from 14 to 21 days."

Sponsored by:
Merial Ltd.

128-409

FOIS 1

1. GENERAL INFORMATION:

- a. File Number: NADA 128-409
- b. Sponsor: Merial Ltd.
3239 Satellite Blvd., Bldg. 500
Duluth, GA. 30096-4640

Drug Labeler Code: 050604
- c. Established Name: Ivermectin
- d. Proprietary Name: IVOMEC (ivermectin) Injection for Cattle and Swine
- e. Dosage Form: Sterile injectable solution
- f. How supplied: 50 mL rubber-capped bottle, and 200, 500, 2 X 500, and 1000 mL soft collapsible packs for use with an automatic syringe
- g. How Dispensed: Over-the-counter (OTC)
- h. Amount of Active Ingredients: 10 mg (1%) ivermectin/mL
- i. Route of Administration: Subcutaneous
- j. Species/Class: Cattle, Swine, Reindeer, American Bison. This supplemental approval only affects cattle.
- k. Recommended Dosage: Cattle: 1 mL for each 50 kg (110 lb) or 200 mcg ivermectin of body weight per kg
- l. Pharmacology Category: Antiparasitic
- m. Indications: For the treatment and control of the following parasites in cattle:
Gastrointestinal Roundworms (adults and fourth-stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*),
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata

Oesophagostomum radiatum

Bunostomum phlebotomum

Nematodirus helvetianus (adults only)

N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Cattle Grubs (parasitic stages):

Hypoderma bovis

H. lineatum

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Mange Mites (scabies)

Psoroptes ovis (syn. *P. communis* var. *bovis*)

Sarcoptes scabiei var. *bovis*

Persistent Activity:

IVOMEC Injection has been proved to effectively control infections and to protect cattle from reinfection with:

Dictyocaulus viviparus for 28 days after treatment; *Ostertagia ostertagi* for 21 days after treatment; and *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment.

- n. Effect of Supplement: To extend the persistent effect periods of *Oesophagostomum radiatum* from 14 to 28 days after treatment and *Cooperia punctata* and *Trichostrongylus axei* from 14 to 21 days after treatment. At this time, the labeling is being revised to reflect updated environmental information and to add the veal calf warning statement to the residue information section.

2. EFFECTIVENESS

a. Dose Characterization

Effectiveness studies were presented in the original NADA 128-409 FOI Summary approval dated February 13, 1984, establishing the recommended dosage of IVOMEC (ivermectin) Injection for Cattle and Swine for the treatment and control of internal and external parasites.

b. Substantial Evidence for Persistent Effectiveness against Endoparasites

Three studies (ASR 1505, 15110, and 15111) conducted to evaluate the persistent activity of IVOMEC (ivermectin) Injection for Cattle and Swine were previously submitted and evaluated using arithmetic means. Subsequent to the original review, the VICH guidance #90 "Effectiveness of Anthelmintics: General Recommendations VICH GL 7" was finalized on March 26, 2001. It allowed for the evaluation of parasite effectiveness studies using geometric means. For each study, the effectiveness was determined by comparing the geometric mean worm counts of the treated groups with those of an untreated control group for each parasite species present in at least six adequately infected control animals. P-values were computed for each parasite species using contrasts in a one-way analysis of variance or unequal-variance t-tests on log-transformed counts, or using Wilcoxon's rank-sum test. The period of persistent activity was defined as the time during which the effectiveness against a genus-species was $\geq 90\%$.

For an indication to be granted, a minimum of two studies is required that have the following characteristics: an adequate level of infection in six control animals, a statistically significant difference between treated and control animals at $P < 0.05$, and 90% or higher efficacies using geometric means for each genus species of parasite and at each persistent effect period. If there are more than 2 studies, then the percent efficacy against a genus species of parasite from each study is added together and divided by the number of studies with that genus species of parasite. If the average is greater than or equal to 90%, then the claim may be granted. These three studies met the above criteria and were reevaluated using geometric means. The overall percent efficacies from three studies for *Trichostrongylus axei* and *Cooperia punctata* at 21 days are 93% and 90%, respectively. Two studies at 28 days for *Oesophagostomum radiatum* both demonstrated percent efficacy $\geq 90\%$. The following claims are granted for IVOMEC (ivermectin) Injection for Cattle and Swine: To extend the persistent effect periods for *Oesophagostomum radiatum* from 14 to 28 days and *Cooperia punctata* and *Trichostrongylus axei* from 14 to 21 days after treatment. The three studies are individually summarized below.

B.1 Study ASR 15065

- 1) Type of Study: Dose confirmation study in cattle with induced infections of

gastrointestinal roundworms.

- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D.
Merial Limited
Fulton, Missouri
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Thirty (30) Holstein calves (10 per group), approximately 4 to 5 months old and weighing 157 to 234 kg at the start of the study were used. All animals were treated with another anthelmintic during the acclimation period to eliminate existing infections.
 - c. Treatment Groups: There were 3 treatment groups. One group received IVOMEC (ivermectin) Injection for Cattle and Swine. The negative controls received no treatment. One group received a medication which is not pertinent to this approval and is not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment according to the following schedule: 1000 L₃ *Trichostrongylus axei* and *Cooperia* spp. Days 1 to 21 and 100 L₃ *Oesophagostomum radiatum* Days 1 to 28. There were larvae of other genus species given for various lengths of time that are not pertinent to this approval and are not reported.
 - e. Dosage Form: IVOMEC (ivermectin) Injection for Cattle and Swine, 10 mg ivermectin/mL.
 - f. Route of Administration: Subcutaneous.
 - g. Dose: 1 mL/50 kg bodyweight (200 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 49 to 50 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 to 50 days after treatment, 28 to 29 days after the last *Trichostrongylus axei* and *Cooperia* spp. larvae were administered and 21 to 22 days after the last *Oesophagostomum radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for the following two genus species. The results are summarized in Table 2.1:

Table 2.1 Study ASR 15065 – Percent Efficacy IVOMEC (ivermectin) Injection for Cattle and Swine 21-Day Persistent Effect Period.

Nematode Species	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy IVOMEC Injection
<i>Cooperia punctata</i>	3169.8	67.9	98
<i>Trichostrongylus axei</i>	3826.9	83.3	98

- 5) Adverse Reactions: There were no adverse reactions in the IVOMEC (ivermectin) Injection for Cattle and Swine group.

B.2 Study ASR 15110

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Edward G. Johnson, D.V.M.
Johnson Research
Parma, Idaho
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Thirty (30) Holstein male calves (24 castrated and 6 intact), approximately 4 to 12 months old and weighing 130 to 186 kg at the start of the study were used. Animals were clear of patent infections at the time of treatment.
 - c. Treatment Groups: There were three groups (10 animals per group). One group received IVOMEC (ivermectin) Injection for Cattle and Swine. The negative controls received no treatment. One group received a medication which is not pertinent to this approval and is not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of the treatment according to the following schedule: *Cooperia punctata* (1000 per day for 21 days), *Trichostrongylus axei* (1000 per day for 21 days), and *Oesophagostomum radiatum* (100 per day for 28 days). There were larvae of other genus species given for various lengths of time that are not pertinent to this approval and are not reported.
 - e. Dosage Form: The dosage form was IVOMEC (ivermectin) Injection for Cattle and Swine, 10 mg ivermectin/mL.

- f. Route of Administration: Subcutaneous.
 - g. Dose: 1 mL/50 body weight (200 mcg ivermectin/ kg body weight) once.
 - h. Test Duration: 49 days of treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 28 days after the last *Cooperia* spp. and *Trichostrongylus axei* larvae were administered and 21 days after the last *Oesophagostomum radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least six control animals for *Cooperia punctata*, *Trichostrongylus axei*, and *Oesophagostomum radiatum*. Efficacy is summarized in Table 2.2:

Table 2.2 Study ASR 15110 – Percent Efficacy IVOMEC (ivermectin) Injection for Cattle and Swine 21-day or 28-day persistent effect periods

Nematode Species	Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Injection
<i>Cooperia punctata</i>	21	1470.7	374.4	75
<i>Trichostrongylus axei</i>	21	588.7	109.7	81
<i>Oesophagostomum. radiatum</i>	28	278.8	24.0	91

- 5) Adverse Reactions: There were no adverse reactions to treatment.

B.3 Study ASR 15111

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D.
Merial Limited
Fulton, Missouri
- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Thirty (30) Holstein heifer calves, approximately 5 to 6 months old and weighing 165 to 268 kg at the start of the study were used. Animals were free of patent infections at the time of infection.
 - c. Treatment Groups: There were 3 treatment groups (10 animals per group). One group received IVOMEC (ivermectin) Injection for Cattle and Swine.

The negative controls received no treatment. One group received a medication which was not pertinent to this approval and is not reported.

- d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Cooperia punctata* (1000 per day for 21 days), *Trichostrongylus axei* (1000 per day for 21 days), and *Oesophagostomum radiatum* (100 per day for 28 days). There were larvae of other genus species given for various lengths of time that were not pertinent to this approval and are not reported.
 - e. Dosage Form: The dosage form was IVOMEC (ivermectin) Injection for Cattle and Swine, 10 mg ivermectin/mL.
 - f. Route of Administration: Subcutaneous.
 - g. Dose: 1 mL/50 kg body weight (200 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 49 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 28 days after the last *Cooperia* spp. and *Trichostrongylus axei* larvae were administered and 21 days after the last *Oesophagostomum radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for *Cooperia punctata*, *Trichostrongylus axei*, and *Oesophagostomum radiatum*. Efficacy is summarized in Table 2.3:

Table 2.3. Study ASR 15111 – Percent Efficacy IVOMEC (ivermectin) Injection for Cattle and Swine 21-day or 28-day persistent effect periods

Nematode Species	Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Injection
<i>Cooperia punctata</i>	21	2917.8	33.5	99
<i>Trichostrongylus axei</i>	21	2122.8	9.9	99
<i>Oesophagostomum radiatum</i>	28	174.2	2.0	99

- 5) Adverse Reactions: There were no adverse reactions to treatment.

3. *TARGET ANIMAL SAFETY*

No further target animal safety data were required from the original approval as discussed in the parent NADA 128-409 FOI summary approval dated February 13, 1984.

4. *HUMAN SAFETY*

No further human safety data were required from the original approval as discussed in the parent NADA 128-409 FOI summary dated February 13, 1984. There is a 35-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and a withdrawal period has not been established for pre-ruminating calves.

5. *AGENCY CONCLUSIONS*

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act, and 21 CFR Part 514 of the implementing regulations. The data demonstrate that IVOMEC (ivermectin) Injection for Cattle and Swine when administered to cattle once at 200 mcg ivermectin/kg body weight is safe and effective for the extension of the following persistent effect periods: for *Oesophagostomum radiatum* from 14 to 28 days after treatment, and *Cooperia punctata* and *Trichostrongylus axei* from 14 to 21 days after treatment.

The following has been added to the residue information section of the labeling: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal".

The Agency has concluded that this product may retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did require a reevaluation of safety or effectiveness data in the parent application. Previously submitted studies were reevaluated using geometric means allowing the persistent effect period for 3 nematode species to be extended.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the extension of the 3 already approved persistent effect indications listed above. Three studies were conducted to provide substantial evidence for these supplemental indications.

No patent information was submitted with this application.

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

- A. 50, 200, and 500 mL – container label and box carton
- B. 2 X 500 mL box carton
- C. 1000 mL – base label, outsert, and box carton
- D. Package insert for 50, 200, and 500 mL container sizes.

3 543'

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Do not contaminate water. Dispose of containers in an approved landfill or by incineration.

INDICATIONS
For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue information and use directions.

WARNING
NOT FOR USE IN HUMANS
Keep this and all drugs out of the reach of children.

NADA 138-10
Approved by FDA Product 41380

Ivomec
(ivermectin)

Injection
for Cattle and Swine

1% Sterile Solution

RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight

50 mL

MERIAL

RESIDUE INFORMATION: Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not treat swine within 18 days of slaughter.

PRECAUTIONS
For subcutaneous injection in cattle and swine only.
Protect product from light.

IVOMEC is a registered trademark of Merial Limited.
Made in The Netherlands.
U.S. Pat. 4,199,569 & 4,853,372.
Merial Limited, Duluth, Georgia, U.S.A.

Unvarnished area
1-1/4"W x 5/16"H

Lot No & Exp. Date ▲ 1020-1492-OF Rev 05-2004

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # **1020-1492-OF**

Client: Ruminant Animal Global Enterprise

Originator: B. Somerville

Country: USA

Brand: Ivomec Cattle & Swine

Project: effective treatment and control facts
disposal statement

Component Description: Syringe Label

Graphic Designer: Patricia Greene

Telephone #: 678-638-3302

Date: 4 May 2004

Revision - Date: A-03/05/04

Note: This revision

history is for internal


GPI purposes ONLY


B-03/22/04

C-05/04/04

Colors:


Use **PANTONE MATCHING SYSTEM**
for an accurate color representation

 **PMS 874**

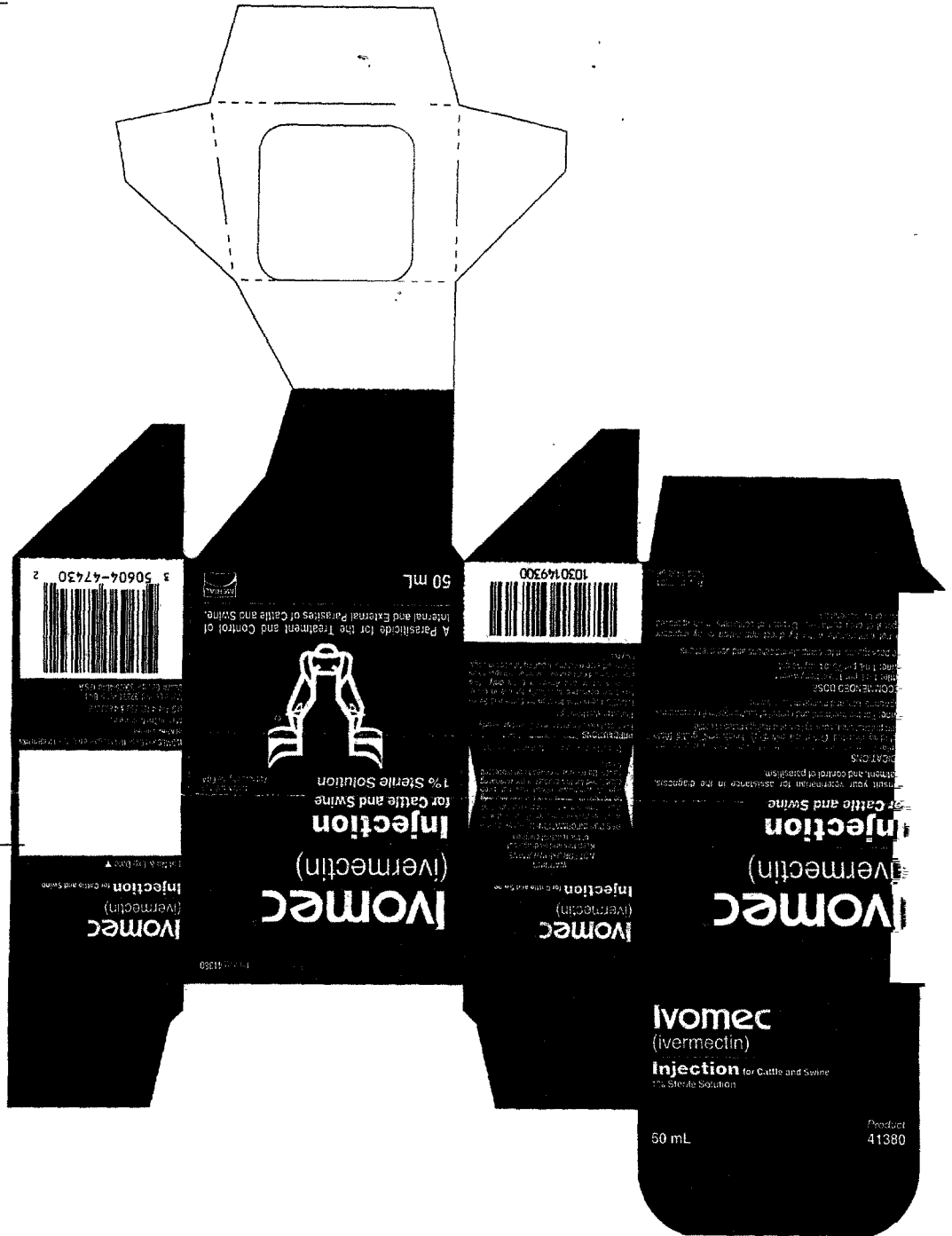
 **Special Brown** (C=0%, M=74%, Y=100% B=80%)

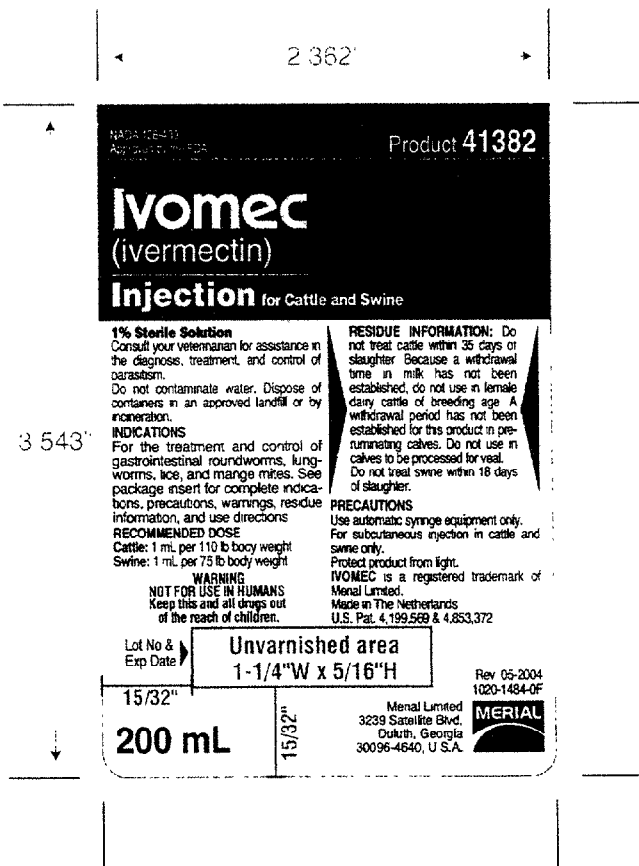
Merial Limited
3239 Satellite Blvd
Duluth, GA 30096, U.S.A.



MERIAL GLOBAL PACKAGING TECHNOLOGY Component # 1030-1493-0F		
Client: Ruminant Animal Global Enterprise Originator: B. Somerville Country: USA Brand: Ivomec Cattle and Swine Project: effective treatment and control face	Component Description: Carton	Graphic Designer: Patricia Greene Telephone #: 678-638-3302 Date: 4 May 2004 Revision - Date: A-02/05/04 Note: Revision B-05/04/04 History is for internal GPT purposes ONLY
Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation. Black PMS 874 Special Brown (C=60%, M=74%, Y=100%, B=80%)	 Merial Limited 2228 Sable Blvd Duluth, GA 30096, USA	

No Varnish Area.
1 1/2" X 1"
(also white)





(Note: Magenta lines do NOT print)

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component # 1020-1484-OF
Client: <u>Ruminant Animal Global Enterprise</u>	Graphic Designer: <u>Patricia Greene</u>	Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation
Originator: <u>B. Somerville</u>	Telephone #: <u>678-638-3302</u>	
Country: <u>USA</u>	Date: <u>4 May 2004</u>	<div style="display: flex; align-items: center;"> <div style="width: 20px; height: 10px; background-color: black; margin-right: 5px;"></div> <div>PMS 874</div> </div> <div style="display: flex; align-items: center;"> <div style="width: 20px; height: 10px; background-color: black; margin-right: 5px;"></div> <div>Special Brown (C=0%, M=74%, Y=100%, B=80%)</div> </div>
Brand: <u>Ivomec Cattle and Swine</u>	Revision - Date: <u>A-03/05/04</u> <i>Note: this revision history is for internal GPT purposes ONLY</i>	
Project: <u>effective treatment and control facs disposal statement</u>		
Component Description: <u>Label</u>		For Merial logo, process should match 3292 for the top of the logo and 326 for the bottom of the logo Merial Limited 3239 Satellite Blvd Duluth, GA 30096, U.S.A.


Colors:
Use PANTONE MATCHING SYSTEM
for an accurate color representation

PMS 874

Special Brown (C=0%, M=74%, Y=100%, B=80%)

For Merial logo, process should match 3292 for the top of the logo and 326 for the bottom of the logo

Merial Limited
3239 Satellite Blvd
Burlington, GA 30096, U.S.A

The Merial logo consists of a stylized 'M' inside a square, with the word 'MERIAL' in a bold, sans-serif font to its right.

Component # 1020-1486-0F

MERIAL GLOBAL PACKAGING TECHNOLOGY

(Note: Magenta lines do NOT print)

Product 41383

IVOMEC (ivermectin)

Injection for cattle and swine

1% Sterile Solution

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not contaminate water. Dispose of containers in an approved landfill or by incineration.

INDICATIONS

Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs (note insect precautions), sucking lice, and mange mites in cattle.

Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice and mange mites in swine.

See package insert for complete indications, precautions, warnings, residue information, and use directions.

RECOMMENDED DOSE

Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight

Exp Date 9/16/00

Lot No & Left

Unannounced area 1-1/4"W x 5/16"H

1/2"

WARNING

NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

RESIDUE INFORMATION: Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-turning calves. Do not use in calves to be processed for veal.

Do not treat swine within 18 days of slaughter.

PRECAUTIONS

Use automatic syringe equipment only when possible. For subcutaneous injection in cattle and swine only. Protect product from light.

IVOMEC is a registered trademark of Menal Limited Made in The Netherlands.

U.S. Pat. 4,199,569 & 4,853,372

Menal Limited
3229 Satellite Blvd
Duluth, Georgia
30096-4640 U.S.A.

Rev 05-2004 1020-1486-05

MERIAL

MERIAL GLOBAL PACKAGING TECHNOLOGY

Component # 1030-1487-0F

Client: Ruminant Animal Global Enterprise
 Originator: B. Somerville
 Country: USA
 Brand: Ivomec Cattle and Swine
 Project: effective treatment and control facts
 Component Description: Carton

Graphic Designer: Patricia Greene
 Telephone #: 678-638-3302
 Date: 4 May 2004
 Revision - Date: A-02/05/04
 Note: this revision history is for internal GPT purposes ONLY

Colors:
 Use PANTONE MATCHING SYSTEM
 for an accurate color representation
 Black
 PMS 874
 Special Brown (C=0%, M=74%, Y=100% B=80%)

Merial Limited
 3239 Satellite Blvd
 Duluth, GA 30096, U.S.A.

Ivomec (ivermectin) Injection for Cattle and Swine 1% Sterile Solution

Ivomec (ivermectin) Injection for Cattle and Swine

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

INDICATIONS

Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, galls (nodule insert precalulations), sucking lice, and mange mites in cattle.

Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

RECOMMENDED DOSE

Cattle: 1 mL per 110 lb body weight

Swine: 1 mL per 75 lb body weight

See package insert for complete indications and use directions.

Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Ivomec (ivermectin) Injection for Cattle and Swine

WARNING

NOT FOR USE IN HUMANS.
 Keep this and all drugs out of the reach of children.

RESIDUE INFORMATION:

Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-maturing calves. Do not use in calves to be processed for veal.

Do not treat swine within 18 days of slaughter.

PRECAUTIONS

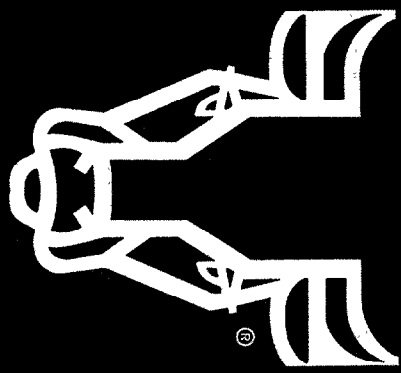
Use automatic syringe equipment only. For subcutaneous injection in cattle and swine only.

Protect product from light. IVM-150C (Ivomec) Injection for Cattle and Swine has been developed specifically for use in cattle, swine, deer, and American bison only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Ivomec (ivermectin) Injection for Cattle and Swine

Ivomec (ivermectin) Injection for Cattle and Swine 1% Sterile Solution

No Varnish Area
 1 1/2" x 1 1/2"
 (also white)




A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine.

500 mL



Rev. 05/2004
 1030-1487-0F

MERIAL GLOBAL PACKAGING TECHNOLOGY		Component # 1030-1488-0F	
Client: Ruminant Animal Global Enterprise		Colors: 	
Originator: Bruce Somerville		For FAMING MATCHING SYSTEM	
Country: USA		Date: 4 May 2004	
Brand: Ivomec Cattle and Swine		Revision: Date 4-04-04	
Project: effective treatment and control facts		Revised for: 6-03-04	
Component Description: Carton		For Animal Use, please consult the label for instructions. Do not use if the seal is broken. Do not use if the seal is broken. Do not use if the seal is broken.	

Ivomec

(ivermectin)

Injection

for Cattle and Swine

1% Sterile Solution

2 x 500 mL

Product
41383

Ivomec

(ivermectin)

Injection

for Cattle and Swine

Ivomec

(ivermectin)

Injection

for Cattle and Swine

1% Sterile Solution

Product 41383

WARNING
NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

RESIDUE INFORMATION: Do not treat cattle within 35 days of a slaughter. Do not treat swine within 30 days of a slaughter. Do not use in horses. Do not use in dogs. Do not use in cats. Do not use in birds. Do not use in fish. Do not use in shellfish. Do not use in honey bees. Do not use in other animals. Do not use in humans. Do not use in pregnant animals. Do not use in nursing animals. Do not use in animals that are to be used for food. Do not use in animals that are to be used for export. Do not use in animals that are to be used for breeding. Do not use in animals that are to be used for research. Do not use in animals that are to be used for other purposes. Do not use in animals that are to be used for any other purpose.

PRECAUTIONS
Use automatic syringe attachment only. For subcutaneous injection in cattle and swine only. Protect product from light. **IVOMEK** (ivermectin) Injection for Cattle and Swine has been developed specifically for use in cattle, swine, horses, and lambs. It is not for use in other animals. This product should not be used in other animals. It is not for use in humans. It is not for use in pregnant animals. It is not for use in nursing animals. It is not for use in animals that are to be used for food. It is not for use in animals that are to be used for export. It is not for use in animals that are to be used for breeding. It is not for use in animals that are to be used for research. It is not for use in animals that are to be used for other purposes.



1030148800

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine.

2 x 500 mL



Ivomec

(ivermectin)

Injection

for Cattle and Swine

Ivomec

(ivermectin)

Injection

for Cattle and Swine

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

INDICATIONS
Cattle: For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs (note insect precautions), sucking lice, and mange mites in cattle.
Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight.
Swine: 1 mL per 75 lb body weight.
See package insert for complete instructions and directions.

Do not contaminate water by direct application. Proper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

No Viable Area
11x11" (plate white)

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3 50604-47444 9

Client: Rumant Animal Global Enterprise		Graphic Designer: Chandra Blumel		Colors: 1 - PANTONE 6510 CMYK SYSTEM	
Owner: Tanya Puchta		Telephone: 678-838-3261		For 10 accurate color reproduction	
Country: USA		Date: 11 July 2013		Black	
Brand: Ivomec Cattle and Swine		Revision: Date: Addendum		CMYK: PMS 674	
Project: Injection 5000L (Metilization)		Revised: Date: Addendum		Special Brown (CMYK: 40% 40% 40% 40%)	
Component Description: Cattle		Product: 41381		MAGNETIC COATINGS	
				MAGNETIC COATINGS	

Ivomec
(ivermectin)
Injection for Cattle and Swine
1% Sterile Solution

Ivomec
(ivermectin)
Injection
for Cattle and Swine

Injection
for Cattle and Swine

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

INDICATIONS
Cattle: For the treatment and control of gastrointestinal roundworms (including pinworms, *Ostodagia ostreiformis*), lungworms, guinea worm (resistant), sucking lice, and mange mites in cattle.
Swine: For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

RECOMMENDED DOSE
Cattle: 1 mL per 110 lb body weight
Swine: 1 mL per 75 lb body weight
See package insert for complete indications and use directions.
Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved facility or by incineration.

Ivomec
(ivermectin)
Injection
for Cattle and Swine

WARNING
NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

RESIDUE INFORMATION:
Do not treat cattle within 55 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-maturing calves. Do not use in calves to be processed for veal.

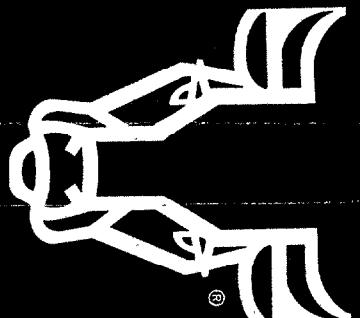
PRECAUTIONS
Use automatic syringe equipment only. For subcutaneous injection in cattle and swine only.
Protect product from light.
Ivomec (ivermectin) Injection for Cattle and Swine has been in cattle, swine, reindeer, and American bison only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Ivomec
(ivermectin)
Injection
for Cattle and Swine

Injection
for Cattle and Swine

1% Sterile Solution

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine.



2013-10-01



1000 mL



50604-47443

No Withdrawal Area.
NADA 141-1111
(Ivermectin)

NOTED: All Cattle and Swine
should be treated with
Ivomec (ivermectin) Injection
US Pat. 4,097,003; 4,097,002
Vet. Label 2002, 2007, 2013
CPL 00071, 00084, 00154

